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| 10/027,134      | 12/20/2001  | Parris S. Wellman    | 102863-0017         | 4419             |

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EXAMINER

ROANE, AARON F

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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3739

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

10/027,134

Applicant(s)

WELLMAN ET AL

Examin r

Aaron Roane

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other:

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## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to an ablation instrument, classified in class 606, subclass 41.
- II. Claims 17-19, drawn to a method of tissue ablating, classified in class 606, subclass 32.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ablation instrument can be used for a tissue process that requires no tissue piercing.

A telephone call was made to Lisa Michaud on September 17, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Upon election of group I, this application contains claims directed to the following patentably distinct species of the claimed invention: Species #1 characterized by figure 4A, Species #1 characterized by figure 4B, Species #3 characterized by figure 4C.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant's election without traverse of Group I (claims 1-16), species III (characterized by figure 4C) in Paper No. 5 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the tissue-contacting conductive surface" in the second to last line. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 8, 10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bissinger et al. (USPN 6,001,096).

Regarding claim 1-3, Bissinger et al. disclose a surgical ablation instrument comprising a first (one of electrode braches 30) and second (the other one of electrode braches 30) member adapted to be placed adjacent to tissue wherein the first and second members are movably to each other and movable between an open and closed position, and a first (one

of electrodes 56) and second (the other one of electrodes 56) conductive element adapted to communicate with a source of ablative energy and effective to transmit ablative energy therebetween, see abstract, col. 3, line 13 through col. 4, line 33 and figures 1, 2a and 2b.

Regarding claims 4, Bissinger et al. further disclose elongated first and second members having proximal ends mated to an actuating member (60) and distal portions (distal segment where 56 is located) having the conductive elements disposed thereon, see col. 3, line 13 through col. 4, line 33 and figures 1, 2a and 2b.

Regarding claim 5, Bissinger et al. further disclose tissue piercing tip (the sharp pointed, most distal tip of 56), see figures 1, 2a and 2b.

Regarding claim 8, Bissinger et al. further disclose the claimed invention. The device can be used in a bipolar manner, therefore inherently one conductive element is used as an active electrode and the other conductive element is used as the return electrode, see abstract, col. 3, line 13 through col. 4, line 33 and figures 1, 2a and 2b.

Regarding claim 10, Bissinger et al. further disclose an insulative coating (50) disposed around a portion of at least one of the first and second members, see abstract, col. 3, line 13 through col. 4, line 33 and figures 3a-c.

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Regarding claim 13, Bissinger et al. disclose a surgical ablation instrument comprising a first (one of electrode braches 30) and second (the other one of electrode braches 30) conductive member adapted to be placed adjacent to tissue wherein the first and second members are movably mated to each other, and a first (one of electrodes 56) and second (the other one of electrodes 56) conductor element adapted to communicate with a source of ablative energy and effective to transmit ablative energy therebetween, see abstract, col. 3, line 13 through col. 4, line 33 and figures 1, 2a and 2b.

Regarding claim 14, Bissinger et al. further disclose tissue piercing tip (the sharp pointed, most distal tip of 56), see figures 1, 2a and 2b.

Regarding claims 15, Bissinger et al. further disclose elongated first and second conductive members having proximal ends mated to an actuating member (60) and distal portions (distal segment where 56 is located) having the conductive elements disposed thereon, see col. 3, line 13 through col. 4, line 33 and figures 1, 2a and 2b.

Claims 1-3, 7, 11, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by

Yamauchi et al. (USPN 6,273,887 B1).

Regarding claim 1-3, Yamauchi et al. disclose a surgical ablation instrument comprising a first (8a) and second (8b) member adapted to be placed adjacent to tissue wherein the first and second members are movably to each other and movable between an open and



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closed position, and a first (the inherent electrical wire connection between 8a and the power supply unit 15) and second (the inherent electrical wire connection between 8b and the power supply unit 15) conductive element adapted to communicate with a source of ablative energy and effective to transmit ablative energy therebetween, see abstract, col. 8-11 and figures 1-4B.

Regarding claim 7, Yamauchi et al. further disclose an embodiment in which a first conductive element (414a) extends from the first member (414) and the second conductive element (440a) extends from the first member (416), see figure 58B.

Regarding claim 11, Yamauchi et al. further disclose that when the handles (6 and 17) are apart the first and second members are in a closed position and when the handles (6 and 17) are together the first and second members are in an open position, see col. 8-11, specifically col. 9, lines 26-56 and figures 1A-4B.

Regarding claim 13, Yamauchi et al. disclose a surgical ablation instrument comprising a first (8a) and second (8b) conductive member adapted to be placed adjacent to tissue wherein the first and second members are movably to each other and movable between an open and closed position, and a first (the inherent electrical wire connection between 8a and the power supply unit 15) and second (the inherent electrical wire connection between 8b and the power supply unit 15) conductor element adapted to communicate

Regarding claim 16, Yamauchi et al. disclose the claimed invention, see the electrodes 71 and 72 in figure 11 and col. 14-15.

Claims 1, 2 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (USPN 6,161,543).

Regarding claims 1 and 2, Cox et al. disclose a surgical ablation instrument comprising a first (one of the two 70 segments) and second (the other of the two 70 segments) member adapted to be placed adjacent to tissue wherein the first and second members are movably to each other and movable between an open and closed position, and a first (one of the two 65) and second (the other of the two 65) conductive elements adapted to communicate with a source of ablative energy and effective to transmit ablative energy therebetween, see abstract, col. 7, line 18 through col. 8, line 26, col. 24, lines 6-41 and figures 4 and 17. Applicant should note

Regarding claim 9, Cox et al. disclose the claimed further limitation of malleability, see col. 34, lines 20-34 and figures 45-47.

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Claims 1-3 and 12 rejected under 35 U.S.C. 102(e) as being anticipated by Tetzlaff et al. (USPN 6,277,117 B1).

Regarding claim 1-3, Tetzlaff et al. disclose a surgical ablation instrument comprising a first (22) and second (24) member adapted to be placed adjacent to tissue wherein the first and second members are movably mated to each other and movable between an open and closed position, and a first (110) and second (120) conductive element adapted to communicate with a source of ablative energy and effective to transmit ablative energy therebetween, see abstract, col. 4, lines 35-67 and figures 1 and 2.

Regarding claim 12, Tetzlaff et al. further disclose a means for biasing (32 and 34) the first and second members in a closed position, see col. 4, lines 48-67 and figure 1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al. (USPN 6,273,887 B1).

Regarding claim 6, Yamauchi et al. disclose the claimed invention. However the claimed invention is explicitly disclosed in two separate embodiments (embodiment 1 characterized by figures 1A-4B and embodiment 2 characterized by figures 56A and 58A-B). The pivoting mechanism (or mated movability) of embodiment #1 could alternatively be used with the first and second member electrode configuration of embodiment #2 to provide another equivalent means of ablating tissue, see abstract, col. 8-11 and figures 1-4B for embodiment #1 and see figure 58B for embodiment #2. The jaw structure of embodiment #2 comprises a first member (414) having a single electrode (414a) while the second member (416) has a first (440a) and a second (440b) electrode, see col. 33, lines 12-67 and figure 58B. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamauchi et al., as taught by another embodiment of Yamauchi et al., to provide the mated movability of the first and second members (embodiment #1) with the jaw structure of another embodiment (embodiment #2) as an alternative yet equivalent means of ablating tissue.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A.R. *A.R.*  
January 14, 2004

*Roy D. Gibson*  
ROY D. GIBSON  
PRIMARY EXAMINER